AWARD NUMBER: W81XWH-16-1-0788

TITLE: Enhancing Quality of Orthotic Services with Process and Outcome Information

PRINCIPAL INVESTIGATOR: Allen Heinemann, PhD

RECIPIENT: Rehabilitation Institute of Chicago
Chicago, IL 60611

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Fort Detrick, Maryland 21702-5012

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6. AUTHOR(S)

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Rehabilitation Institute of
Chicago dba Shirley Ryan
AbilityLab
355 E. Erie Street,
Chicago, IL 60611

8. PERFORMING ORGANIZATION REPORT NUMBER

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The objective of this proposed project is to develop data collection modules that can be used to improve the quality of services for users of ankle-foot orthoses (AFOs), the largest group of orthosis users. Three specific aims are:
1. Identify issues that are important to the quality of care for AFO users as well as items and instruments that can be used to assess these quality issues.
2. Evaluate and validate patient-reported outcome instruments using performance instruments.
3. Specify items required for quality measure development and design data collection modules that can be used in quality improvement efforts and to demonstrate accountability of health care delivery.

15. SUBJECT TERMS

None provided

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TABLE OF CONTENTS

1. INTRODUCTION:

Orthotic device use by Service members and Veterans is growing, yet outcomes assessment and quality measure development for orthotic services lags far behind other healthcare specialties. Orthotists acknowledge the value of quality measures, but cannot adopt measures used in other healthcare settings because they have not been validated for orthosis users. Thus, the objective of this project is to develop data collection modules that can be used to improve the quality of services for users of ankle-foot orthoses (AFOs), the largest group of orthosis users. This project applies state-of-the-art methods in quality measure development to a large and growing population that has not benefitted from sustained research. An Advisory Committee representing multiple stakeholders will specify criteria for quality measures that are relevant to AFO users. These specifications will guide selection of proposed process and outcome instruments with optimal psychometric properties that are feasible for use in busy clinics. We will assess orthotists' perceptions of barriers and facilitators of quality data with an online survey. Data collection with these instruments is planned at two Veterans Hospitals (Hines, Minneapolis) and the Shirley Ryan AbilityLab. Patient-reported and performance measures will be obtained from 100 patients with trauma etiologies and other neurological disorders. We will examine content, concurrent and discriminant, and known-group validity of the patient-reported instruments; calculate minimal detectable change; examine floor and ceiling effects; compute correlations between patient-reported and performance measures; and evaluate sensitivity to change. We will design specifications for data collection and obtain feedback about usability and feasibility from the Advisory Committee.

2. KEYWORDS:

Stroke, Paralysis, Neurological, Braces, Orthosis, Orthoses, Trauma, Cerebrovascular, Stability, Gait, Balance, Postural

3. ACCOMPLISHMENTS:
What were the major goals of the project?

Preparatory Activities
Milestone: IRB Approval at all sites (Months 1-6); 100% complete

Task 1.1 Prepare for and convene and Advisory Committee that represents multiple stakeholders to identify important issues in the quality of care for AFO users.
Milestone: Identification of important issues in the quality of care for AFO users (Months 1-6); 100% complete

Task 1.2 Identify items and instruments that operationalize important quality of care concepts for AFO practice
Milestone: Identification of items and instruments that operationalize important quality of care concepts for AFO practice (Months 1- 6); 60% complete

Task 1.3 Survey orthotists, physical therapists, and patients to understand their preferences, priorities and barriers to quality measure use.
Milestone: Survey completed and results compiled (Months 7-9); 70% complete

Task 1.4 Define case-mix indicators – additional critical data elements needed for valid interpretation of quality measures
Milestone: Identification of case mix issues (Months 7-9); 60% complete

Task 2.1 Select process and outcome items and instruments with optimal properties identified in Task 1.2
Milestone: Selection of process and outcome items and instruments (Months 10-11)

Task 2.2 Collect patient-reported and performance-based data and evaluate test-retest reliability, concur-rent validity, sensitivity to change, and respondent/clinician burden in a sample of 100 AFO users
Milestone: Data set of 50 reliability sample and 50 sensitivity sample cases (Months 13-23)

Task 3.1 Review results of Task 2.2 and recommend components of quality measures to the Advisory Committee
Milestone: Quality measure components reported to Advisory Committee (Months 22-24)

Task 3.2 Prioritize and select the most compelling quality measures
Milestone: Priority list of quality measures (Months 25-27)

Task 3.3 Design the specifications for data collection and obtain usability and feasibility feedback from the Advisory Committee
Milestone: Design specifications for a clinical interface (Months 28-30)

Task 3.4 Disseminate findings and promote knowledge translation
Milestone: Broad dissemination of study findings (Months 31-36)

What was accomplished under these goals?

Task 1.1 Prepare for and convene and Advisory Committee that represents multiple stakeholders to identify important issues in the quality of care for AFO users.

18 advisory committee members agreed to participate.

- They represent multiple stakeholders including Orthotist and Prosthetic Network Management, Orthotic Manufacturers, Orthotists, Patient Organizations, Patient Perspective (including veteran representatives), Professional Organizations, Software Developer, Researcher, and Walter Reed Hospital Representative.

The first in-person advisory committee meeting took place March 1, 2017.

- Provided input/guidance in identifying items and instruments (see task 1.2).

Quarterly advisory committee phone call took place May 17, 2017.

- Provided input on focus group transcript coding and advised on the upcoming online survey.
- Provided continued input on the ongoing literature review.

Quarterly advisory committee phone call took place August 30, 2017.

- Provided input and advised survey development.
- Provided continued input on the ongoing literature review.
- Provided input on manuscripts in development (see achievement descriptions under tasks 1.2 and 1.3 below).

Task 1.2 Identify items and instruments that operationalize important quality of care concepts for AFO practice

We are completing a systematic review of the literature, using the expertise of a communications coordinator and education Librarian at Northwestern University to create a search strategy tailored to the aims of this study.

- We have completed the initial search and are completing summary tables in accordance with PRISMA reporting guidelines.

A former RIC project manager and current master's student in Northwestern Universities Prosthetic and Orthotics program joined our team January 16, 2017 to provide additional expertise regarding literature reviews on quality of care concepts for orthotics practice.

We shared results of the literature review with the advisory committee on March 1, 2017; May 17, 2017; and August 30, 2017.

Based on the results from the literature review and the feedback from the advisory board meeting, we have developed a systematic literature review paper that discusses quality assessment measures. **The paper is 80% complete.**

Task 1.2 (continued)

The abstract for the manuscript describing the systematic review of custom AFO instruments follows:

Objective: To identify instruments that assess ankle-foot orthosis (AFO) use in persons with traumatic and neurological etiologies and determine to what extent they are useful for assessing quality of care for AFO users.
Data Sources: PubMed, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase, Cochrane Systematic Reviews, Cochrane Central Register of Controlled Trials, and the Physiotherapy Evidence Database (PEDro).
Study Design: Systematic review.
Data Collection/Extraction Methods: Literature was reviewed from January 25 and April 3, 2017 using multiple key words. Two reviewers independently evaluated the title and abstract of potential articles, selected articles for full text review, compared and reconciled their selections and resolved discrepancies by consensus. One reviewer extracted type of population, orthosis and instrumentation from the full text of each included article, and the second reviewer confirmed selection. A list of instruments and frequency of use was generated, and instruments were categorized by data collection method (performance-based, patient-reported or clinician-rated performance), International Classification of Functioning, Disability and Health (ICF) code for domain of measurement for health status or functional assessment instruments, and quality measure domain as described by the National Quality Forum.
Principal Findings: The review yielded 79 articles reporting data for 29 unique instruments that were used in more than one study.
Conclusions: The identified instruments address quality of care topics may be used to develop quality indicators for orthotic practice, specifically custom AFOs.

Task 1.3 Survey orthotists to understand their preferences, priorities, and barriers to quality measure use.

On November 5th, 2016, we completed one focus group with 10 certified orthotists. Based on the feedback provided from the first focus group, we decided to schedule 1 additional focus group of certified orthotists and 1 focus group of physical therapists, as they are often involved with the quality of care for orthotic users.

- Focus group with Certified Orthotists, November 5, 2016: 10 participants
- Focus group with Certified Orthotists, January 26, 2017: 7 participants
- Focus group with Physical Therapists, February 4, 2017: 7 participants
- Focus group with AFO Users, May 15, 2017: 5 participants
- **Total: 29 participants**

Task 1.3 (continued)

The abstract for the manuscript describing the focus group follows:
Study Design: Qualitative, focus groups of orthotists, physical therapists, and patients.
Background: There is widespread recognition in the orthotics and prosthetics industry of the need to measure quality relevant to orthotic practice. The American Academy of Orthotists and Prosthetists and the International Society for Prosthetics and Orthotics organized consensus conferences that illustrate that nearly all areas of orthotic practice require extensive research on quality measurement.
Objective: Assess orthotists', physical therapists', and patients' perspectives on indicators of quality of care for patients using custom ankle-foot orthoses.
Methods: We conducted focus groups with users of custom ankle-foot orthoses (AFOs), orthotists, and physical therapists. A stenographer took verbatim notes and provided a transcript of each discussion. Research staff members used a thematic coding approach to summarize the transcripts.
Results: Seventeen orthotists, seven physical therapists and five custom AFO users participated in four separate focus groups. Participants discussed structural, process, and outcome indicators of care quality relevant for custom AFO users. We identified 28 thematic codes addressing 10 broad aspects of quality-of-care relevant for AFO users. Many of the themes reflect the National Quality Forum's (NQF) core concepts of person- and family-centered care.
Conclusions: Focus groups of orthotists, physical therapists, and custom AFO users identified quality concepts that provide guidance for the selection and development of quality measures.

We are completing development of the Redcap online survey which will be used survey orthotists nationally.

Task 1.4 Define case-mix indicators – additional critical data elements needed for valid interpretation of quality measures
We have reviewed findings from Advisory Committee input to date, focus groups, and literature review.

We are compiling a list of case-mix indicators to be presented to the Advisory Committee after the completion, analysis, and review of the national orthotist online survey.

What opportunities for training and professional development has the project provided?

Nothing to report

How were the results disseminated to communities of interest?

Dr. Heinemann shared results of the focus group component of this project during the Brain Injury Association of Illinois annual meeting in Oak Brook Terrace, Illinois on September 20, 2017.

Dr. Heinemann will share results of the focus group and the literature review during the Midwest Chapter of the American Academy of Orthotists Prosthetists during its Fall One Day Education Symposium on Saturday, November 11, 2017.

Dr. Heinemann will share results of the focus group and the literature review to the Rehabilitation Outcomes Conference organized by the Fujian University of Traditional Chinese Medicine in Fuzhou, China on November 16, 2017.

What do you plan to do during the next reporting period to accomplish the goals?

We will distribute a nationwide survey to orthotists and physical therapists working in VA hospitals and private settings regarding quality concepts that should be a focus of measurement and standardized assessments that could measure quality concepts. A draft of the survey is available at https://redcap.nubic.northwestern.edu/redcap/surveys/?s=JFFRR8N77P.

We will submit documents to IRBs at Northwestern University, Minneapolis VA, and Hines VA as well as HRPO to permit primary data collection.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

We proposed in our application to obtain focus group input only from orthotists. The Advisory Committee helped us appreciate the patients' perspectives are critical and that physical therapists have a critical role in delivery of custom AFO services. Thus, we added a focus group to obtain physical therapist input and a focus group to obtain input from custom AFO users.

Actual or anticipated problems or delays and actions or plans to resolve them

Adding focus group so physical therapists and custom AFO users took longer than we proposed when we only planned orthotist input. While we are a few months behind schedule, we are able to accelerate activities in year 2 and 3 to get back on schedule.

Changes that had a significant impact on expenditures

The project manager assigned to this project resigned her position in February 2017; we were not able to fill the position until June 2017. Her replacement left the organization in October. Thus, our budget is underspent as a consequence. We anticipate committing extra effort to reduce under expenditure of contracted resources.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals

Not applicable

Significant changes in use of biohazards and/or select agents

Not applicable

6. PRODUCTS:

Publications, conference papers, and presentations

Journal publications.

Nothing to report

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers and presentations.

Dr. Heinemann shared results of the focus group component of this project during the Brain Injury Association of Illinois annual meeting in Oak Brook Terrace, Illinois on September 20, 2017.

Dr. Heinemann will share results of the focus group and the literature review during the Midwest Chapter of the American Academy of Orthotists Prosthetists during its Fall One Day Education Symposium on Saturday, November 11, 2017.

Dr. Heinemann will share results of the focus group and the literature review to the Rehabilitation Outcomes Conference organized by the Fujian University of Traditional Chinese Medicine in Fuzhou, China on November 16, 2017.

Website(s) or other Internet site(s)

https://www.sralab.org/node/13434

Technologies or techniques

Nothing to report

Inventions, patent applications, and/or licenses

Nothing to report

Other Products

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Rehabilitation Institute of Chicago dba Shirley Ryan AbilityLab

Name:	Allen Heinemann
Project Role:	Principal Investigator
Research Identifier:	None
Nearest person month worked:	3.42
Contribution to Project:	Dr. Heinemann created a focus group guide; moderated focus groups; coded transcripts; generated quality themes/codes; drafted a focus group manuscript; ran advisory board meetings and keep project activities aligned with protocol timeline.
Funding Support:	None

Name:	Jordyn Durkin
Project Role:	Research Assistant
Research Identifier:	None
Nearest person month worked:	2.48
Contribution to Project:	Ms. Durkin recruited certified orthotists for two focus groups; coded transcripts; developed a codebook of quality themes; scheduled an advisory board meeting and organized weekly meetings.
Funding Support:	None

Name:	Arielle Goldsmith
Project Role:	Project Manager
Research Identifier:	None
Nearest person month worked:	2.7
Contribution to Project:	Ms. Goldsmith supervised two research assistants; kept project activities aligned with timelines, organized an advisory board meeting; reserved flight and hotel accommodations for advisory participants; and modified project protocol.
Funding Support:	None

Name:	Sara Jerousek
Project Role:	Research Temp
Research Identifier:	None
Nearest person month worked:	1.53

Contribution to Project: Ms. Jerousek performed literature searches; reviews; assisted with writing the literature review paper and assisted with IRB modifications.
Funding Support: None

Name: Erik Schuster
Project Role: Project Manager
Research Identifier: None
Nearest person month worked: 1.68
Contribution to Project: Mr. Schuster supervised support staff; created REDCap codebook and survey and assisted with IRB modifications.
Funding Support: None

Name: Patrick Semik
Project Role: Data Analyst
Research Identifier: None
Nearest person month worked: 2.08
Contribution to Project: Mr. Semik works on data and statistical analysis for this project.
Funding Support: None

Name: Jamal Spraggins
Project Role: Research Assistant
Research Identifier: None
Nearest person month worked: 3.43
Contribution to Project: Mr. Spraggins recruited physical therapists for a focus group; coded transcripts; assisted with the development of quality themes; scheduled an advisory board meeting and created a demographics table for the focus group manuscript.
Funding Support: None

Northwestern University

Name: Stefania Fatone
Project Role: Subsite PI
Researcher Identifier : None
Nearest person month worked: 2.37
Contribution to Project: Collaborate with project PI especially in terms of study development, project management, orthotic management expertise, and data interpretation.
Funding Support: None

Chicago Association for Research & Education in Science (CARES)

Name:	Sherri LaVela, PhD
Project Role:	Subcontract PI
Researcher Identifier :	None
Nearest person month worked:	1.8
Contribution to Project:	Participants in weekly team meetings. Helps plan methods and study strategies. Recruitment site activities, helps recruit participants and helps develop data collection tools. Dissemination efforts -- helps author manuscripts.
Funding Support:	None

Name:	Rodney Stuck, MD
Project Role:	Co-Investigator
Researcher Identifier :	None
Nearest person month worked:	0.6
Contribution to Project:	Helps with recruitment of VA staff for focus groups. Provides clinical/content expertise.
Funding Support:	VA funds

Name:	Ibuola Kale
Project Role:	Research Coordinator
Researcher Identifier :	None
Nearest person month worked:	1.2
Contribution to Project:	Helps with recruitment efforts. Primary contact for IRB efforts at Hines VA. Participants in team meetings and discussion.
Funding Support:	None

Department of Veterans Affairs- Minneapolis VA Health Care System

Name:	Michelle D. Peterson, DPT
Project Role:	Site PI
Researcher Identifier :	None
Nearest person month worked:	2.4
Contribution to Project:	Preparation of regulatory documents (initial IRB, R&D, resubmission IRB), participation in advisory committee (assist in developing committee nominees, conference call attendance, review of committee findings) participation in bi-weekly conference calls, manuscript review, survey development.
Funding Support:	None

Name:	Billie C.S. Slater, MA
Project Role:	Study Coordinator
Researcher Identifier :	None
Nearest person month worked:	3
Contribution to Project:	Preparation of regulatory Documents including Initial IRB Application, participated in bi-weekly conference calls, participated in coding of focus group transcripts.
Funding Support:	None

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Allen Heinemann

New Awards

W81XWH-17-1-0157 (Heinemann& Jayaraman) 9/1/17-8/31/19
1.8 CM (15%)
DOD $709,197
Evaluating the Utilization and Efficiency of Wearable Exoskeletons for SCI Rehabilitation
The goal of this application is to acquire information that will guide evaluation strategies, training strate-gies, and clinical decision plans to enable the safe and effective use of robotic exoskeletons to enhance mo-bility in Veterans and civilians with SCI.
Specific Aims:

1. Describe the interest in, perceived need for, and expected outcomes of exoskeletons among persons with SCI who have not received robotic therapy with exoskeletons.
2. Describe the perceived benefits, limitations, and costs of exoskeletons among persons with SCI who re-ceived exoskeleton therapy during SCI rehabilitation or in the community, and compare their perspectives with persons who have no exoskeleton experience.
3. Describe physical therapists', physicians', other stake holders' experiences, clinical evaluation and train-ing strategies using exoskeleton therapy in rehabilitation and community settings.

Contracting/Grants Officer: Amber Stillrich
Grant Specialist
USA MED RESEARCH ACQ ACTIVITY
820 Chandler St.
Fort Detrick MS 21702

90SI5009-02-00 (Chen/Heinemann) 10/01/11 – 09/29/17(NCE)
0.24 CM (2%)
NIDILRR- H133N110014 $2,414,304
Midwest Regional Spinal Cord Injury Care System
The goals of MRSCICS are to advance the outcomes of our previous Model Systems research, continue to study the effectiveness of innovative treatment strategies; and evaluate the benefits of a well-designed, comprehensive, coordinated, interdisciplinary continuum of care that lead to improved outcomes for persons with SCI.
Specific Aims:
1. Provide a comprehensive continuum of care for persons with SCI.
2. Contribute to assessment of long-term outcomes by enrolling 80 subjects per year into the national SCI database.
3. Conduct one site-specific study

4. Disseminate research findings to various stakeholders in an effective and timely manner.
5. Collaborate effectively with the Model System Knowledge Translation Center.
6. Involve individuals with disabilities in research and dissemination activities.
Role: Co-PI

Contracting/Grants Officer: Dr. Kenneth Wood
330 C Street SW, 2511B
Administration for Community Living
Washington, DC 20201

5K12HS023011-01 (Cella) 9/1/14-7/31/19
0.24 CM (2%)
AHRQ $25,000
Northwestern University Patient-centered intervention and Engagement Training
Goal of Dr. Daniel Pinto's project is to provide a clear path to independence beginning with an innovative idea, that is, to identify the global problem of adherence to the attributes that are associated with adherence, apply preference weights tot the relative importance of these attributes using choice modeling, and build patient-centered physical activity recommendations based on an individual's preferred attributes.
Role: Faculty Mentor

Contracting/Grants Officer: Tylor Carl
Office for Sponsored Research
Northwestern University
750 N. Lake Shore Dr. 7th Floor
Chicago, IL 60611

90SI5022-01-00(Chen/Heinemann) 9/30/16-9/29/21
3 CM (25%)
NIDILRR $2,420,000
The Midwest regional spinal cord injury model system
The goal of this project is to investigate the effect of dAIH alone and in combination with high-intensity task-specific training on upper extremity function in individual with chronic incomplete cervical SCI.
Specific Aims:

1. Quantify the effects of dAIH therapy on hand and arms strength, and hand dexterity in persons with incomplete tetraplegia.
2. Evaluate the benefits of combined dAIH therapy and high-repetition task-specific upper extremity training on arm and hand strength, and hand dexterity in persons with tetraplegia.

Role: Co-Principal Investigator

Contracting/Grants Officer: Dr. Kenneth Wood
330 C Street SW, 2511B
Administration for Community Licing

Washington, DC 20201

W81XWH-16-01-0788 (Heinemann) 9/30/16-9/29/19
3 CM (25%)
DOD/CDMRP
$1,590,406
Enhancing quality of orthotic services with process and outcome information
Goal of this project is to help the Defense Health Program improve understanding of the benefits of orthotic devices, treatments, and rehabilitation strategies.
Specific Aims:

1. Identify issues that are important to the quality of care for AFO users as well as instruments that can be used to assess these quality issues.
2. Evaluate and validate patient-reported outcome instruments using performance instruments.
3. Specify items required for quality measure development and design data collection modules that can be used in quality improvement efforts and to demonstrate accountability of health care delivery.

Contracting/Grants Officer: Elena G. Howell
Grants Officer
USA MED RESEARCH ACQ ACTIVITY
820 Chandler St.
Fort Detrick MS 21702

Craig H. Neilsen Foundation (Kisala)**367686** 4/30/16-4/30/18
0.6 CM (5%)
Clinical Adaption of the SCI-QOL Psychosocial Measures
$297,000
Goal of this project is to improve psychosocial outcomes such as emotional well-being and quality of life in individuals with SCI.
Specific Aims:

1. Establish clinically relevant scoring standards (i.e., score cut points) for the SCI-QOL Ability to Participate, Depression, Anxiety, and Resilience item banks;
2. Employ a state of the art quantitative/qualitative mixed methodology technique with extensive consumer participation to enhance the clinical relevance of the scoring standards;
3. Apply these standards to assess statistically significant change using existing SCI-QOL data sets and to develop different profiles of psychosocial adjustment following SCI;
4. Conduct a gold-standard validation study of the Depression and Anxiety cut points.Methods:

Role: Site PI

Contracting/Grants Officer: Angela Alcaraz
University of Delaware

210 Hullihen Hall
Newark, DE 19716

H133P130013 (Heinemann) 10/1/13-9/30/18
0.6 CM (5%)
NIDILRR $60,0000
Advanced Rehabilitation Research Training in Health Services Research

Goal of this project/Specific Aims: The goal of this project is to provides an integrated, interdisciplinary, collaborative training program for early career scholars focusing on rehabilitation-related health services research. Health services faculty work closely with fellows to provide a rigorous and relevant interdisciplinary curriculum, integrating faculty and programs from diverse departments and centers into a unified health services research training Through this program, six post-doctoral fellows will develop new skills to enhance their previous training in order to pursue a research career in rehabilitation-related health services research. program includes carefully matched mentors, didactic course work, original research, grant writing, and scientific publishing over a two-year period.

Contracting/Grants Officer: Margaret Campbell
NIDILRR, Administration for Community Living
U.S. Department of Health and Human Services
330 C Street SW
Washington, DC 20230

90ARPO0001-01-00 (Heinemann) 9/30/17-9/29/22
0.6CM (5%)
NIDILRR $750,000
Northwestern University Policy Research Fellowship
The overall Goal is to train four individuals who intend to focus their career on policy issues pertaining to disability, independent living, or rehabilitation during a 2-year fellowship.

Specific Aims
1. Recruit and train highly qualified trainees in advanced policy research methods, focused on disability, independent living, or rehabilitation policy;
2. Provide trainees with an immersive, residential experience in the application of disability policy research;
3. Provide trainees with robust mentorship for a disability policy research project; and
4. Continuously monitor and improve the effectiveness of the ARRT DPRF-NU.

Contracting/Grants Officer: Marlene Spencer,
Grants Officer
NIDILRR, Administration for Community Living
U.S. Department of Health and Human Services
330 C Street SW
Washington, DC 20230

Stefania Fatone

New Award

Title:	Functional Assistance Provided by Myoelectric Elbow wrist hand orthoses
Time commitments:	0.60 calendar months (Principal Investigator)
Supporting agency:	Myomo Inc. Industry Sponsored Clinical Trial
Name and address of the Funding Agency's Procuring Contracting/Grants Officer:	Steve Kelly President & COO Myomo, Inc One Broadway, 14th floor Cambridge MA 02142 617.444.9661
Performance period:	4/27/17 – 7/7/20
Level of funding:	$112,407
Brief description of the project's goals:	The purpose of this project is to compare upper extremmity (UE) movement while wearing the MyoPro Motion-G versus a resting hand splint and no device in stroke survivors with moderat eUE dysfunction.

Title:	Longitudinal Observation of Myoelectric Upper Limb Orthosis Use among Veterans with Upper Limb Impairment (W81XWH-16-1-0773)
Time commitment:	1.15 calendar months (Principal Investigator)
Supporting agency:	Orthotics and Prosthetics Outcomes Research Program (OPORP) Orthotics Outcomes Research Award (OORA)
Performance period:	9/30/16 to 9/29/19
Level of Funding:	$500,000
Brief description of the Project goals:	The objective of this observational study is to document longitudinal outcomes in Veterans with the myoelectric upper limb orthosis with powered elbow and grasp using both patient-centric performance and patient-reported outcome measures. Longitudinal observation will allow us to detect both the initial therapeutic effects as well as the later functional outcomes of orthosis use.

List of the specific aims:	Aim 1: Evaluate therapeutic effects of myoelectric upper limb orthosis. Aim 2: Evaluate functional effects of myoelectric upper limb orthosis
Title:	iGRAB: Innovative Glove for Rehabilitation and Assistance using Biomimicry
Time commitment:	1.86 calendar months (Sub-contract PI)
Supporting agency:	DHP SBIR Phase II
Name and address of the Funding Agency's Procuring Contracting/Grants Officer:	Micaela Bowers, Contracting Officer USA Med Research Acq Activity 820 Chandler Street Fort Detrick, MD 21702
Performance period:	1/1/16 to 12/31/17
Level of Funding:	Subcontract Total Cost: $198,097
Brief description of the Project goals:	The aim of the iGrab is to provide assistance to hand function resulting from hand injury during rehabilitation and every day activities. Efficacy of the device in terms of assisting grasping activities in persons with impaired hand function must be demonstrated. Therefore, quantitative clinical evaluation of hand function with and without the iGrab will be evaluated in persons with impaired hand function due to both stroke and hand trauma.
List of the specific aims:	We propose to conduct a before-and-after trial of 30 subjects (15 with stroke and 15 with traumatic hand injury).
Title:	Enhancing Quality of Orthotic Services with Process and Outcome Information
Time commitment:	2.37 calendar months (Co-Investigator)
Supporting agency:	Orthotics and Prosthetics Outcomes Research Program (OPORP) Orthotics Outcomes Research Award (OORA)
Performance period:	9/30/16- 9/29/19
Level of Funding:	SubK amount: $150,994

Brief description of the Project goals:	The goal of this application is to develop data collection modules that can be used to improve the quality of services for users of custom-fabricated ankle-foot orthoses (AFOs).
List of the specific aims:	Project objectives are to: A1. Identify issues that are important to the quality of care for custom AFO users as well as items and instruments that can be used to assess these quality issues. A2. Evaluate and validate patient-reported outcome instruments using performance instruments. A3. Specify items required for quality measure development and design data collection modules that can be used in quality improvement efforts and to demonstrate accountability of health care delivery.
Title:	No longer smooth: introducing striations into prosthetic socket construction to improve suspension, rotation, fit and comfort (W81XWH-16-1-0485)
Time commitment:	1.15 calendar months (Co-Investigator)
Supporting agency:	CDMRP CRMRP NMSIRA 2015
Performance period:	9/30/16-9/29/19
Level of Funding:	$674,666
Brief description of the Project goals:	The objective of this pre-clinical research project is to investigate the effect of different types of texturing on suspension, rotation, fit, and comfort. We hypothesize that horizontal striations will improve suspension while vertical striations will help control transverse plane rotation.
List of the specific aims:	The specific aims are to: (1) Test the force needed to displace the socket longitudinally and rotationally; (2) Test the coefficient of friction, tensile and static strength of sockets with different texturing patterns; and (3) Test the comfort and fit of textured sockets on Veterans with transtibial amputation.

Completed Awards

Title:	Development of Sub-Ischial Prosthetic Sockets with Assisted-Vacuum Suspension for Highly Active Persons with Transfemoral Amputations W81XWH-10-1-0744

Time commitments:	1.8 calendar months (Principal Investigator)
Supporting agency:	Department of Defense Peer Reviewed Orthopedic Research Program (PRORP) Technology Development Award
Name and address of the Funding Agency's Procuring Contracting/Grants Officer:	Vera Pollard USA MED RESEARCH ACQ ACTIVITY Fort Detrick MD 21702 Phone: (301) 619-7264 Email: VERA.POLLARD@AMEDD.ARMY.MIL
Performance period:	9/15/10 – 09/14/16
Level of funding:	$2,099,865
Brief description of the project's goals:	The objective of this proposal is to develop prosthetic socket technology that will maintain residual limb volume; improve active range of motion of the hip; and increase comfort during sitting, standing, walking, and running in highly active transfemoral prosthesis users, allowing users to be more active.
List of the specific aims:	Aims 1 and 2. Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users. Aim 3. Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis. Aim 4. Evaluate system performance with transfemoral prosthesis users. Aim 5. Develop education materials for sub-ischial socket design.

Title:	Evaluating outcomes of dysvascular partial foot and transtibial amputation: a systematic review and development of shared decision making resources
Time commitments:	1.2 calendar months (Co-Investigator)
Supporting agency:	American Orthotic and Prosthetic Association
Name and address of the Funding Agency's Procuring Contracting/Grants Officer:	Thomas F. Fise, Executive Director 330 John Carlyle Street, Suite 200, Alexandria, VA 22314 P: 571-431-0802 F: 571-431-0899 tfise@AOPAnet.org
Performance period:	7/1/15 – 6/30/16
Level of funding:	$59,005
Brief description of the	The aim of this project will be to compare the outcomes of

project's goals: people with partial foot and transtibial amputation secondary to peripheral vascular disease and/or diabetes as well as translate what we learn from this research to help clinicians and patients make well-informed decisions about amputation surgery.

List of the specific aims: We propose to conduct a two-part systematic review. The first part will critically appraise recent evidence describing the incidence of partial foot and transtibial amputation, wound healing, complications, secondary amputations, and mortality. The second part will appraise research focusing on the functional and psychosocial outcomes of partial foot or transtibial amputation; specifically, outcomes related to walking, community mobility, participation, quality of life, as well as common experiences associated with limb loss such as depression and anxiety.

Sherri L. LaVela (Dr. LaVela replaces Dr. Pape at CARES, all her active supports are listed)

Active Support

W81XWH-16-SCIRP-QRA LaVela (PI) 10/01/2017 – 09/30/2020
3.6 calendar
Department of Defense $569,840
Perspectives and Preferences for Weight Management after Spinal Cord Injury
●The goals of this study are to understand the experiences, barriers, and facilitators encountered by persons with SCI, their informal caregivers, and their health care providers, and to assess their expectations of and preferences for weight management strategies using in-depth qualitative interviews and focus groups will be used

PVA 821 LaVela (PI) 06/01/2017 – 05/31/2018
2.4 calendar
Paralyzed Veterans of America Education Foundation Grant $49,705
Developing a Curriculum on Grief/Loss due to SCI for Health Providers
●The goal of this study is to develop a curriculum to educate health providers and persons with SCI about potential consequences of feelings of grief/loss due to injury, how to prevent their occurrence, and if they do occur, how to deal with and overcome these feelings.

W81XWH-16-1-0788 OP150034 LaVela (site PI) 09/31/2016 – 10/01/2020
2.4 calendar
Department of Defense $600,000
Enhancing Quality of Orthotic Services with Process and Outcome Information
●The major goal of this project is to identify quality measures and develop data collection modules that can be used to improve the quality of services for users of ankle-foot orthoses (AFOs).

LaVela/Raad (Co-PI) 11/30/2015 – 10/31/2017
2.0 calendar
Craig H. Neilsen Foundation. Psychosocial Research Grants $150,000
Development of a Comprehensive Screening Protocol for Depressive Symptoms in People Living with SCI.
The goal of this study is to develop a depression screening tool for individuals with SCI that can be used across settings and for individuals with varying levels and severity of injury.

Rodney Stuck
No Change

Deutsch
Completed Awards
HHSP23320095651WC, Task Order HHSP23337033T; (Morley) 09/09/13 – 09/30/17
0.80 calendar month
Examine the Impact of Using Continuity Assessment Record and Evaluation (CARE) Data in the Current Medicare Fee for Service (FFS) Case Mix Methodologies
Role: senior analyst (co-investigator)
Officer: Susan Bogasky
Department of Health and Human Services, Assistant Secretary for Health and Human Services
200 Independence Avenue, SW Washington, D.C. 20201
Goal: Examine potential updates to the post-acute care prospective payment systems using standardized assessment iems.

Michelle Peterson
No Change

What other organizations were involved as partners?

Organization Name: Northwestern University
Location of Organization: 750 N. Lake Shore Drive, 7th Floor, Chicago, IL 60611
Partner's contribution to the project
- Facilities;
- Collaboration;

Organization Name: Chicago Association for Research & Education in Science (CARES)
Location of Organization: (if foreign location list country): Building One, Rm C303, 5000 S. 5th Avene, Hines, IL 60141
Partner's contribution to the project
- Financial support: Cost share Dr. Stuck's effort
- Facilities;
- Collaboration;

Organization Name: Department of Veterans Affairs- Minneapolis VA Health Care System
Location of Organization: One Veterans Drive, Minneapolis, MN 55417
Partner's contribution to the project

- Facilities;
- Collaboration;

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not Applicable

QUAD CHARTS: See Below

Enhancing Quality of Orthotic Services with Process and Outcome Information

OP150034

PI: Allen Heinemann

Organization: Rehabilitation Institute of Chicago

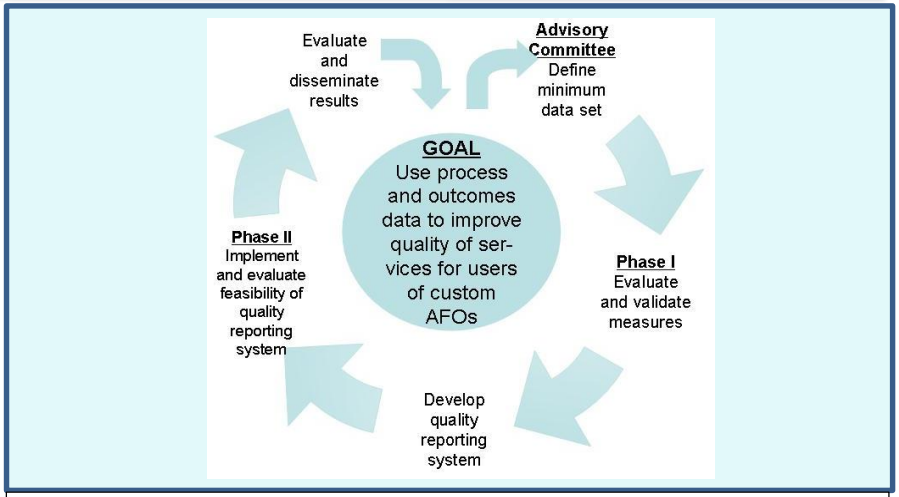
Award Amount: $1,590,406.00

Study/Product Aim(s)

- Identify issues that are important to the quality of care for AFO users as well as items and instruments that can be used to assess these quality issues.
- Evaluate and validate patient-reported outcome instruments using performance instruments.
- Specify items required for quality measure development and design data collection modules that can be used in quality improvement efforts and to demonstrate accountability of health care delivery.

Approach

This proposal builds on our on-going quality measure development efforts by identifying items and instruments that can be used to create quality measures that meet the criteria set forth by the National Quality Forum (NQF), the leading organization responsible for endorsing quality measures. In order for quality measures to be effective, they must be tailored to orthotic practice. This project engages stakeholders in the selection and development of measures that can be used to document quality of care for patients receiving custom AFOs.



Our team has PCORI funding to evaluate suitability of PRO measures for use during inpatient rehabilitation for patients with neurological disorders. No investigator has evaluated PRO measures for orthotics users as described in the figure above.

Timeline and Cost

Activities CY	16	17	18
1. Identify issues			
2. Evaluate outcome instruments			
3. Specify quality measures			
Budget ($1,590,406)	**$538,232**	**$516,989**	**$535,185**

Updated: October 23, 2017

Goals/Milestones

Project Year 1 Tasks

T1.1 Prepare for and convene an Advisory Committee that represents multiple stakeholders to identify important issues in the quality of care for AFO users.

T1.2 Identify items and instruments that operationalize important quality of care concepts for AFO practice.

T1.3 Survey orthotists to understand their preferences, priorities & barriers to quality measure use.

T1.4 Define case-mix indicators – additional critical data elements needed for valid interpretation of quality measures.

T2.1 Select process and outcome items and instruments with optimal properties identified.

Project Year 2 Tasks

T2.2 Collect patient-reported and performance-based data and evaluate test-retest reliability, concurrent validity, sensitivity to change, and respondent/clinician burden in a sample of 100 AFO users.

Project Year 3 Tasks

T3.1 Review results and recommend quality measure components to the Advisory Committee.

T3.2 Prioritize and select the most compelling quality measures.

T3.3 Design the specifications for data collection and obtain feedback about usability and feasibility from the Advisory Committee.

T3.4 Disseminate findings and promote knowledge translation.

Budget Expenditure

Projected Expenditure: $1,590,406.00

Actual Expenditure: $349,348.28

Indicators of Quality Care for Custom AFOs

This survey will require about 10 minutes to complete. To do so, you will:
(1) Rate the importance of several quality of care topics,
(2) Tell us how much time you would be willing to spend collecting quality information during a patient's episode of care, and
(3) Rate the utility of several measures of patient performance and patient-reported outcome measures.

The purpose of this survey is to obtain input about quality of care indicators for custom ankle-foot orthoses (AFOs). We are interested in learning how orthotists and physical therapists define high quality care for individuals who need custom AFOs. Your input is critical in assuring that healthcare policy makers focus on the issues that you deem to be important in defining healthcare quality for custom AFO users.

This survey is part of a research study, "Enhancing Quality of Orthotic Services with Process and Outcome Information" funded by the United States Department of Defense; Northwestern University's Institutional Review Board approved this survey (IRB # STU00203034).

All information you provide will be anonymous and remain confidential. We do not ask for your name or other personally identifiable information. We are happy to provide a summary of results.

To request a summary of results, please contact the principal investigator, Allen Heinemann at a-heinemann@northwestern.edu.

Begin Survey -- If you wish to go to a previous page, please click "Previous Page" instead of the "Back" button

1) What is your age?

_____
(If you choose not to answer, enter "N/A")

2) What is your sex?

◯ Male
◯ Female
◯ Decline to answer

3) What is your position title?

◯ Certified Orthotist
◯ Physical Therapist
◯ Other
◯ Decline to answer

Please specify:

_____

4) How many years of experience do you have working with patients who use custom AFOs?

_____
(If you choose not to answer, enter "N/A")

5) What is the highest degree you have completed?

◯ High School Diploma
◯ Bachelor's Degree
◯ Post-baccalaureate Certificate
◯ Master's Degree
◯ Doctoral Degree
◯ Decline to answer

6) In what type of facility do you work most of the time?

Please select one.

◯ Part of a multi-facility practice-publicly owned
◯ Part of a multi-facility practice-privately owned
◯ Single-location practice-privately owned
◯ Hospital or rehabilitation center
◯ VA facility
◯ University-based clinic or facility
◯ Academic or educational institution (training/research)
◯ Central fabrication facility
◯ Other
◯ Decline to answer

Please specify:

_____

Background

By way of background, hospitals and clinics typically seek to improve the quality of patient care by focusing on three characteristics:
(1) Structural characteristics - such as - Does a clinic use electronic medical records? Does a clinic hire certified orthotists?
(2) Process characteristics - such as - Does a clinic use a safety checklist?
(3) Outcome characteristics - such as - What is the AFO success/failure rate 60 days after delivery?

The National Quality Forum defines Quality Measures that address issues like:
(1) Timely and effective care - e.g., How long do patients wait to receive an appointment?
(2) Avoidable complications - e.g., Do patients experience pain while wearing an AFO?
(3) Readmissions - e.g., Does a patient develop a skin breakdown within 90 days of receiving a new device?
(4) Unnecessary use of services - e.g., Does a patient return repeatedly for minor adjustments to the AFO?

We can collect quality measure data from several sources, including:
(1) Clinicians' ratings of patient health status, when functional status is important,
(2) Patients' performance on standardized assessments such as timed walking tests, range of motion, and strength, etc.
(3) Patient-Reported Outcome Measures. These measures include patients' experience of care and health status, such as pain level or having all of one's questions answered.

7) Standardized Assessments

For each patient, please report how much time could you devote to administering standardized assessments for quality measurement purposes.

a) How much time could you devote to administering standardized assessments for quality measurement purposes during an initial evaluation?

◯ 0 minutes
◯ up to 5 minutes
◯ 10 minutes
◯ 15 minutes
◯ 20 minutes
◯ 25 minutes
◯ 30 minutes or more
◯ Decline to answer

b) How much time could you devote during a fitting appointment?

◯ 0 minutes
◯ up to 5 minutes
◯ 10 minutes
◯ 15 minutes
◯ 20 minutes
◯ 25 minutes
◯ 30 minutes or more
◯ Not Applicable
◯ Decline to answer

c) How much time could you devote during a delivery appointment?

◯ 0 minutes
◯ up to 5 minutes
◯ 10 minutes
◯ 15 minutes
◯ 20 minutes
◯ 25 minutes
◯ 30 minutes or more
◯ Not Applicable
◯ Decline to answer

d) How much time could you devote during subsequent visits?

◯ 0 minutes
◯ up to 5 minutes
◯ 10 minutes
◯ 15 minutes
◯ 20 minutes
◯ 25 minutes
◯ 30 minutes or more
◯ Decline to answer

In the following questions, please rate how essential the following themes are in evaluating the quality of AFO services.

Environment of Care

How essential is information about Environment of Care to evaluating the quality of custom AFO services?

Environment of Care refers to the facility's Accessibility, Layout, and Ambiance.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Environment of Care

a) How essential is Accessibility of the facility?

Accessibility refers to the facility being in a convenient location and ease of entrance and exit to all patients.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is a facility's Layout?

Layout refers to the facility having adequate space and having equipment that is organized in an efficient manner that enhances delivery of care.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

c) How essential is the facility's Ambiance?

Ambiance refers to the facility being clean, providing privacy, and being calm and inspiring.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Organizational Characteristics

How essential is information about Organizational Characteristics to evaluation of the quality of custom AFO services?

Organizational Characteristics include Courtesy of Reception Staff, Ease of Scheduling, Timeliness of Device Delivery, and Collection of Meaningful and Actionable Data.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Organizational Characteristics

a) How essential is the Courtesy of Reception Staff?

The Courtesy of Reception Staff includes demonstrating courtesy, politeness, and empathy.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is Ease of Scheduling?

Ease of Scheduling refers to patients being able to schedule appointments easily.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

c) How essential is Timeliness of Device Delivery?

Timeliness of Device Delivery refers to the facility's ability to deliver services in a streamlined and efficient manner.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

d) How essential is Collection of Meaningful and Actionable Data?

Collection of Meaningful and Actionable Data refers to the facility collecting data that are useful for care delivery and quality improvement.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Clinician Competency

How essential is information about Clinician Competency to evaluating the quality of custom AFO services?

Clinician Competency refers to maintaining industry standards of education and training.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Clinician Competencies

a) How essential is Clinician Education and Experience?

Clinician Education and Experience refers to clinicians having the education and years of experience to deliver high quality services.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is a Comprehensive Evaluation?

Comprehensive Evaluation refers to clinicians conducting comprehensive evaluations of patients' function, goals, and situations.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

c) How essential is Clinical Certification and Continuing Education?

Clinical Certification and Continuing Education refers to clinicians maintaining appropriate certification by completing continuing education.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Patient Communication

How essential is information about Good Patient Communication to evaluating the quality of custom AFO services?

Patient Communication refers to Clinician Follow-Up with Patients, Establishing and Maintaining Rapport, Setting Patient Goals, and Patient Education.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Patient Communication

a) How essential is Clinician Follow-Up with Patients?

Follow-Up refers to clinicians scheduling follow-up appointments and answering patients' questions.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is Establishing and Maintaining Rapport?

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

c) How essential is Setting Patient Goals?

Setting Patient Goals refers to clinicians developing goals and individualized treatment plans and communicating their expectations for patients and themselves.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

d) How essential is Patient Education?

Patient Education refers to clinicians providing instruction on how to use a device including donning, doffing, wearing schedule, care for the device, and maintenance procedures.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Care Coordination

How essential is information about Care Coordination to evaluating the quality of custom AFO services?

Care Coordination refers to Continuity of Care and Documentation of Assessment and Services.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Care Coordination

a) How essential is Continuity of Care?

Continuity of Care refers to how the facility assures continuity of care by clinicians and coordinates care with other providers.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is Documentation of Assessment and Services?

Documentation of Assessment and Services refers to clinicians documenting assessments and services in a manner that allows other clinicians and facilities to coordinate care.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Device Characteristics

How essential is information about Device Characteristics to evaluating the quality of custom AFO services?

Device Characteristics includes: Material Quality, Device Durability, Device Adjustability, Device Modifiability, and Device Weight.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Device Characteristics

a) How essential is Material Quality?

Material Quality refers to the device being constructed of suitable materials that are durable and provide the intended benefits.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is Device Durability?

Device Durability refers to the device being durable and maintaining its integrity.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

c) How essential is Device Adjustability?

Device Adjustability refers to patients being able to adjust the device as appropriate to meet their needs.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

d) How essential is Device Modifiability?

Device Modifiability refers to the device being easily modified to enhance ideal fit and performance.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

e) How essential is Device Weight?

Device Weight refers to the device weight being acceptable to the patient.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Device Usage

How essential is information about Device Usage to evaluating the quality of custom AFO services?

Device Usage reflects: Patients' Evaluation of Cosmesis, Social Confidence Wearing Device, Ease of Donning and Doffing, and Adherence to Device Use.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Device Usage

a) How essential is Patients' Evaluation of Cosmesis?

Cosmesis refers to the patient evaluating the device's appearance favorably.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is Social Confidence Wearing the Device?

Social Confidence Wearing the Device refers to the patient feeling comfortable wearing the device in social settings.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

c) How essential is Ease of Donning and Doffing?

Ease of Donning and Doffing refers to the patient's ability to don and doff the device easily.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

d) How essential is Adherence to Device Usage?

Adherence to Device Use reflects the patients' ability and willingness to follow recommendations of device use.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Device Fit and Comfort

How essential is information about Device Fit and Comfort to evaluation of the quality of custom AFO services?

Device Fit and Comfort refers to conformability of the device to the patient's body and level of comfort.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Device Fit and Comfort

a) How essential is it that the patient experiences minimal pain or discomfort wearing the device?

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is it that the patient experiencing no skin damage from the orthosis?

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Body Function

How essential is information about Body Function to evaluating the quality of custom AFO services?

Body Function includes: Gait Speed, Gait Pattern, Walking Endurance, Joint Range of Motion, Balance, and Beneficial Function.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Body Function

a) How essential is Gait Speed?

Gait Speed refers to the device allowing a comfortable and desirable walking speed.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is Gait Pattern?

Gait Pattern refers to the device enhancing walking pattern.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

c) How essential is Walking Endurance?

Walking Endurance refers to the device maximizing walking endurance.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

d) How essential is Joint Range of Motion?

Joint Range of Motion refers to the device maximizing range of motion.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

e) How essential is Balance?

Balance refers to the device enhancing balance.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

f) How essential is Enhancement of Patient Function in evaluating quality of a custom AFO?

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Activity and Participation

How essential is information about Activity and Participation to evaluating the quality of custom AFO services?

Activity and Participation includes: Activity Level and Independence and Quality of Life.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

Please rate the following themes within Activity and Participation

a) How essential is Activity Level and Independence?

Activity Level and Independence refers to the device's ability to enhance the patient's activity level and independence.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

b) How essential is Quality of Life?

Quality of Life refers to a device enhancing the patient's perception of the impact health status has on quality of life.

◯ Essential
◯ Desirable
◯ Optional
◯ Irrelevant

9) Sources of Information

For each of the themes you rated as essential, please indicate the best source from which to collect the quality information.

Check all that apply:

For Ease of Scheduling, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Records collected by the facility

For Timeliness of Device Delivery, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Records collected by the facility

For Clinician Follow-Up with Patients, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Records collected by the facility

For Continuity of care, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Records collected by the facility

For Material Quality, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance

For Device durability, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance

For Device adjustability, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance

For Device Modifiability, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance

For Device Weight, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance

For Ease of Donning and Doffing, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance

For Adherence to Device Use, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Records collected by the facility

For Skin Integrity, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance

For Gait Speed, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Patient performance on a standardized assessment

For Gait Pattern, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Patient performance on a standardized assessment

For Walking Endurance, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Patient performance on a standardized assessment

For Joint Range of Motion, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Patient performance on a standardized assessment

For Balance, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Patient performance on a standardized assessment

For Beneficial effect of the device, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Patient performance on a standardized assessment

For Activity Level and Independence, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Patient performance on a standardized assessment

For Quality of Life, please indicate how the quality information should be collected.

☐ Patient self-report
☐ Clinician observation of patient performance
☐ Patient performance on a standardized assessment

10) The following is a list of standardized assessments used in AFO research.

Please indicate for each instrument whether you are familiar or not familiar with its use in clinical practice.

Borg Rating of Perceived Exertion (BPE)

◯ Familiar
◯ Not Familiar

Stroke Impact Scale (SIS)

◯ Familiar
◯ Not Familiar

Ankle Passive Range of Motion using a goniometer

◯ Familiar
◯ Not Familiar

10 meter walk test (10MWT)

◯ Familiar
◯ Not Familiar

5 meter walk test (5MWT)

◯ Familiar
◯ Not Familiar

6 minute walk test (6minWT)

◯ Familiar
◯ Not Familiar

Modified Emory Functional Ambulation Profile (mEFAP)

◯ Familiar
◯ Not Familiar

Timed Up and Go (TUG)

◯ Familiar
◯ Not Familiar

Timed Up and Down Stairs (TUDS)

◯ Familiar
◯ Not Familiar

Berg Balance Scale (BBS)

◯ Familiar
◯ Not Familiar

Fugl-Meyer Assessment (FMA)

◯ Familiar
◯ Not Familiar

Modified Ashworth Scale (MAS)

◯ Familiar
◯ Not Familiar

Functional Ambulation Categories (FAC)

◯ Familiar
◯ Not Familiar

Functional Independence Measure (FIM® instrument)

◯ Familiar
◯ Not Familiar

Rivermead Mobility Index (RMI)

◯ Familiar
◯ Not Familiar

Physiological Cost Index (PCI)

◯ Familiar
◯ Not Familiar

Are you currently using any Patient Reported Outcomes Measures?

◯ Yes
◯ No

Outcomes Measure 1:

_____

Outcomes Measure 2:

_____

Outcomes Measure 3:

_____

Outcomes Measure 4:

_____

Outcomes Measure 5:

_____

Are you currently using any Patient Performance Measures?

◯ Yes
◯ No

Performance Measure 1:

_____

Performance Measure 2:

_____

Performance Measure 3:

_____

Performance Measure 4:

_____

Performance Measure 5:

_____

11) For the instruments with which you are familiar, please rate the extent to which the data from use of the instrument is a good indicator of high quality care for custom AFOs.

Borg Rating of Perceived Exertion (BPE)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Stroke Impact Scale (SIS)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Ankle Passive Range of Motion using a goniometer

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

10 meter walk test (10MWT)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

5 meter walk test (5MWT)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

6 minute walk test (6minWT)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Modified Emory Functional Ambulation Profile (mEFAP)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Timed Up and Go (TUG)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Timed Up and Down Stairs (TUDS)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Berg Balance Scale (BBS)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Fugl-Meyer Assessment (FMA)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Modified Ashworth Scale (MAS)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Functional Ambulation Categories (FAC)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Functional Independence Measure (FIM® instrument)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Rivermead Mobility Index (RMI)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

Physiological Cost Index (PCI)

◯ Very much a good indicator
◯ Somewhat of a good indicator
◯ Not at all a good indicator
◯ Unsure if a good indicator

12) For the instruments with which you are familiar, please rate the feasibility of using the standardized assessment during your appointment with the patient.

Borg Rating of Perceived Exertion (BPE)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Stroke Impact Scale (SIS)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Ankle Passive Range of Motion using a goniometer

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

10 meter walk test (10MWT)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

5 meter walk test (5MWT)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

6 minute walk test (6minWT)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Modified Emory Functional Ambulation Profile (mEFAP)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Timed Up and Go (TUG)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Timed Up and Down Stairs (TUDS)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Berg Balance Scale (BBS)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Fugl-Meyer Assessment (FMA)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Modified Ashworth Scale (MAS)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Functional Ambulation Categories (FAC)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Functional Independence Measure (FIM®)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Rivermead Mobility Index (RMI)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

Physiological Cost Index (PCI)

◯ Very feasible
◯ Somewhat feasible
◯ Not feasible
◯ Unsure

You have reached the end of the survey.

In the comment box below, please describe any feedback you may have about the survey and its components.

This step is optional and the information you provide will be used to inform the research team of aspects the survey did not capture.

Comment Box

To request a summary of results, please contact the principal investigator, Allen Heinemann at a-heinemann@northwestern.edu.